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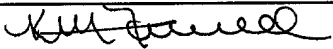
<b>UTILITY PATENT APPLICATION TRANSMITTAL</b>  <i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>	Attorney Docket No.	0156-2001	Total Pages	17
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VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

DOCKET NUMBER  
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Applicant or Patentee: Michael A. Lebner

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Filed or Issued:

Title: BANDAGE FOR WOUND OR INCISION CLOSURE

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NAME OF SMALL BUSINESS CONCERN: Renbel, Inc.

ADDRESS OF SMALL BUSINESS CONCERN: 66 Maugus Avenue  
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SIGNATURE

DATE

11/19/99

## BANDAGE FOR WOUND OR INCISION CLOSURE

### Background of the Invention

Compositions and methods for wound or incision closure are known in the art. The use of sutures or staples to  
5 close a wound or incision represents the most common of these prior art techniques. The use of sutures or staples is an invasive technique which can be painful and frequently the use of an anesthetic is required. These processes often leave unsightly scars, both from the insertion holes and  
10 from varying tensions applied to the wound or surgical incision between the suturing points and intervening spaces. Moreover, these methods necessitate follow-up visits to a hospital or doctor's office for removal.

Although other compositions and methods for closing  
15 wounds or incisions are known in the art, these have not gained popular acceptance due to limitations in their design. There is a clear need for non-, or less invasive method for wound or incision closure which is practical and easy to use.

### Summary of the Invention

The present invention relates to a bandage for closing a wound or incision. The invention was originally disclosed in compliance with the U.S. Patent Office Disclosure Document Program as Disclosure Document Numbers 448,944 and  
25 446,186. In a preferred embodiment, the bandage comprises a first flat flexible component having adhesive on a lower surface and a plurality of first elongated connectors extending from one edge thereof in a first direction. The bandage further comprises a second flat flexible component  
30 having adhesive on a lower surface and one or more second elongated connectors extending from one edge thereof in a second direction generally opposite to the first direction. A first pulling element is joined to the first elongated connectors and adapted for lateral translation of the first

flat flexible component toward a wound edge. A second pulling element is joined to the second elongated connectors and adapted for lateral translation of the second flat flexible component toward the wound edge. The pulling elements tend to spread the pulling force provided by a person applying the bandage of the present invention across each of the elongated connectors to which it is attached. A means for attaching the first elongated connectors to the second flat flexible component and means for attaching the second elongated connectors to the first flat flexible component are provided.

The adhesives provided on the lower surface of the first and second flat flexible components are selected based on their compatibility with the skin, as well their ability to securely hold the bandage for a period of time sufficient for the wound to heal. A variety of such adhesives are known in the art. Prior to application, the adhesives are protected from contamination and oxidation by one or more sheets of a protective film. The film is removed prior to application of the bandage thereby exposing the adhesive.

In embodiments of the present invention in which the first and second flat flexible components are thin and extremely flexible, the adhesive protecting film may be selected to provide a degree of stiffness which aids in application of the bandage. Multiple protective films may be provided to protect the adhesive on a single flat flexible component, thereby providing convenient locations to grip the top and protected bottom of the bandage with the fingers during application.

The means for attaching the first elongated connectors to the second flat flexible component, and the second elongated connectors to the first flat flexible component, are also, in preferred embodiments, adhesives. When the flat flexible components are applied, and a desired tension is reached effecting wound or incision closure, the

elongated connectors are brought into contact with the flat flexible components and an adhesive fixes their positions relative to one another. It will be recognized that during manufacture, the adhesive may be applied to the upper  
5 surfaces of the flat flexible components, to the lower surfaces of the elongated connectors, or to both. A variety of pressure sensitive adhesives are appropriate for this application and the choice of which adhesive to employ is largely one of design choice and optimization. As was  
10 discussed above in connection with the adhesive on the lower surfaces of the flat flexible components, the adhesives are protected prior to application with a thin removable film.

The sizes of the various components are variable within parameters defined by functional considerations. For  
15 example, the length of the first and second flat flexible components (i.e., in a dimension generally parallel to the wound or incision), must be approximately the same length as the wound or incision to effect closure. To a large extent, the length of the first and second flat flexible components  
20 (which is determined based on the length of the wound or incision) determines the width of the first and second flat flexible components (i.e., the dimension perpendicular to the length of the first and second flat flexible components in the plane of application). In other words, the  
25 relationship of length to width must be selected such that sufficient adhesive may be applied to hold the bandage in place once applied to the skin. If the width of the bandage is too small, relative to its length, the bandage will be insecure when applied and susceptible to premature and  
30 unintended separation from the skin. The determination of length to width ratios are empirical in nature and adhesive-dependent. Generally speaking, an acceptable length to width ratio may be from about 1:2 to about 8:1. These ratios are provided as examples, with no attempt being made  
35 to provide maximum or minimum ratios.

Another consideration which relates to the sizing of the elements of the bandage of the present invention is the spacing between the elongated connectors. It is important that there be sufficient space between adjacent elongated  
5 connectors to allow adjustment of the first and second flat flexible components relative to one another. More specifically, in application, one of the two flat flexible components is applied to the skin before the other flat flexible component. Following application, this flat  
10 flexible component is not easily removed and repositioned. Therefore, having sufficient spacing between the elongated connectors is important to facilitate fine adjustment of the unattached flat flexible component relative to the attached flat flexible component. There is no absolute minimum which  
15 can be stated with respect to spacing between elongated connectors. Preferred ranges are probably best stated as a percentage of the bandage length. For example, a spacing between adjacent elongated connectors of between about 5% to about 10% of the bandage length (as defined above) is an  
20 example of an appropriate range.

In preferred embodiments, the flat flexible components, elongated connectors, and pulling elements described in the preceding paragraph are produced from a substantially inelastic polymeric material. Alternatively, they may be  
25 produced from an elastic material which is reinforced with an inelastic structural component thereby rendering the device substantially inelastic. For example, such inelastic materials may include monofilament polymeric line or mesh. Reinforcement of the flat flexible components along the  
30 wound edge, and of the pulling elements, is preferably done using a material which is both rigid and inelastic (e.g., a rigid polymer is a preferred material for this purpose).

In preferred embodiments, the flat flexible elements, elongated connectors and pulling elements are produced from  
35 sheet stock (e.g., plastic sheet stock). Die cutting these



elements from plastic sheet stock to provide monolithic components which are subsequently joined to produce a functional bandage is a particularly cost-effective approach. The sheet stock may be perforated to allow for the exchange of air with the skin beneath the bandage. The thickness of the sheet stock may vary depending upon application. In addition, as discussed above, portions may be reinforced with a rigid material as needed.

In preferred embodiments, the first and second pulling elements are removable following application of the bandage to the skin. This feature minimizes the bandage size following application to the patient. This decrease in the overall size of the bandage reduces the chance that a portion of the bandage may be caught, for example, on clothing or a pillow. Such an occurrence could tend to pull the bandage away from the skin thereby causing the wound or incision to open. Minimizing the overall size of the bandage following application also tends to provide for a more comfortable fit.

A preferred design which provides for the removal of the pulling elements includes in-line perforations or scoring along the first and second elongated connectors. By breaking the elongated connectors along these perforations, the first and second pulling elements are removed.

In a preferred embodiment of the bandage of the present invention, the first and second elongated connectors are interleaved. The interleaving of the elongated connectors can be effected in a variety of ways which will be apparent to one of skill in the art. By way of example, at least one member of the pair of flat flexible components and elongated connectors may be die cut as a single unit, while die cutting the corresponding pulling element separately. The first and second elongated connectors may then be interleaved, followed by attachment of the individually die

cut pulling element to the appropriate elongated connectors using, for example, an adhesive.

Another method for assembling an interleaved embodiment is most readily described by way of example. A first  
5 monolithic component comprising a pulling element, a pair of first elongated connectors and a first flat flexible component is provided. A second monolithic component comprising a pulling element, three second elongated connectors and a second flat flexible component is provided.  
10 The elongated connectors are spaced such that they would interleave, if mated, but for the fact that the middle second elongated connector (being fixed at each end) prohibits the mating of the two elements. In order to mate the two monolithic components it is necessary to cut this  
15 middle second elongated connector, mate the two monolithic components such that the elongated connectors interleave, then reattach the middle second elongated connector. Clearly this method of assembling applies also to embodiments having more than 5 total elongated connectors.

20 An alternative to the interleaved embodiments described above has been termed the wide key-hole design. In this design, two monolithic components are manufactured (e.g., by a die cut process). Each of the two monolithic components comprise a first flat flexible component, elongated  
25 connector(s) and a pulling element. The elongated connector(s) of the first monolithic component are all adjacent one another and centrally located in the assembled and applied bandage. The elongated connectors of the second monolithic component flank those of the first monolithic  
30 component lying toward the outside edges of the bandage. This design facilitates manufacture because both monolithic components can be die cut in a conventional manner, then the first monolithic component may be inserted into the relative wide opening between the two sets of elongated connectors in  
35 the second monolithic component. When rotated into the same

plane, as they are when applied, the monolithic components engage one another resulting in a preferred embodiment of the present invention.

When applied to the skin and appropriately tensioned,  
5 one edge of the first flat flexible component and one edge of the second flat flexible component are position nearest to and substantially parallel to the wound or incision. These edges will be referred to herein as the wound edges. In preferred embodiments of the present invention, the wound  
10 edges are adapted to evert (or raise) skin edges to promote wound healing. It is known in the art that everting, raising or mounding of the skin edges at the wound or incision site prevents wound inversion. One way in which this may be accomplished is to provide a bend at the wound  
15 edge. The bend may angled or arcuate. The adhesive on the lower portion of the flat flexible components is also applied to the portion of the wound edge. When attached to the skin this eversion edge tends to lift the edges of the skin at the point of closure contact thereby promoting wound  
20 or incision healing.

As mentioned above, preferred embodiment of the present invention include die cut embodiments. In such embodiment, the elongated connectors may be viewed as strap-like in their dimensions. In preferred embodiments, a portion of  
25 the elongated connectors is cut away to increase the unobstructed surface area over the wound or incision. This tends to facilitate drainage of exudates and application of medication. This cut-away is best made in a die cut process.

In preferred embodiments, the bandage of the present invention is also adapted for wound closure alignment. Spacing between adjacent elongated connectors, as discussed above, is relevant to the issue of wound closure alignment. Additionally, preferred embodiments of the bandage of the  
35 present invention include wound closure alignment

indicators. These alignment indicators are visual indicators which appear on the flat flexible components near the wound edge. Typically, they will appear as a line or an arrow generally perpendicular to the wound or incision. In closing a wound or incision, a clinician typically closes the wound manually with his/her fingers at the approximate mid-point, then makes a small mark or line perpendicular to the wound with a surgical pencil. These marks are used to align the device precisely with the wound alignment indicators on the bandage of the present invention.

The bandage of the present invention can be optionally adapted for transdermal drug delivery. As is known in the art, a drug is deliverable transdermally through the skin. For such an application, a drug-containing patch is secured to at least one of the flat flexible components in such a way that the drug can be delivered through the skin. Given the fact that there will be no adhesive contact between the skin and the flat flexible component in the area of the drug delivery patch, it may be necessary to increase the size of the flat flexible component to secure the bandage in such a transdermal drug delivery embodiment. Transdermal drug delivery is well known in the art and a review of the background is not necessary to enable one of skill in the art to make and use the present invention.

The bandage of the present invention may optionally include an elastic tension indicator element. The purpose of the tension indicator element is to provide a visual indication that a desired tension has been reached while applying the bandage. For example, materials are known in the art which change color when a predetermined tension is applied. Similarly, other graphic representations may be used for this purpose. For example, a rectangular graphic representation may be applied to an elastic tension indicator element. As this tension indicator is stretched, the graphic representation of the rectangle stretches. This

element may be designed such that the desired tension is indicated when the original rectangular representation is stretched to the point where it closely approximates a geometric square.

- 5        It is desirable that this elastic tension indicator element be removable with the pulling elements following application of the bandage. At a minimum, the elastic tension indicator element should be positioned in the bandage such that when the bandage is applied, it is not possible for the elastic element to continue to stretch and release the desired tension previously established.
- 10

The present invention also relates to a method of wound closure. The method comprises applying the bandage described above in the manner specified.

15    Brief Description of the Drawings

Fig. 1 is a perspective view illustrating a bandage of the present invention in a non-tensioned state.

Fig. 2 is a perspective view illustrating a bandage of the present invention with tension applied.

- 20        Fig. 3 is a perspective view illustrating a bandage of the present invention with elongated connectors secured to flat flexible components and pulling elements removed.

- Fig. 4 is a perspective view illustrating a bandage of the present invention in non-tensioned a wide-keyhole embodiment.
- 25

Fig. 5 is a perspective view of a protective cover for application over the bandage of the present invention.

- Fig. 6 is a perspective view of the protective cover of Fig. 6, applied to protect a bandage of the present invention.
- 30

Detailed Description of Preferred Embodiments

A bandage of the present invention in a non-tensioned state is depicted in Fig. 1. Bandage (1) includes a first

flat flexible component (5) and a second flat flexible component (25). Each of these components has an upper surface to which lead lines 5 and 25 are directed, and lower surfaces which are not visible in the drawing. The lower surfaces are coated with adhesive to facilitate attachment to the skin. A plurality of first elongated connectors (15) extend from the wound edge (20) of the first flat flexible component (5) in a first direction, and a plurality of second elongated connectors (35) extend from the wound edge (42) of the second flat flexible component in a second direction which is generally opposite to the first direction. A first pulling element (40) is joined to the first elongated connectors (15) and adapted for lateral translation of the first flat flexible component (5) toward a wound or incision. Similarly, a second pulling element (45) is joined to the second elongated connectors (35) and adapted for lateral translation of the second flat flexible component (25) toward the wound or incision. In preferred embodiments, the means for attaching the first elongated connectors (15) to the second flat flexible component (25), and the second elongated connectors (35) to the first flat flexible component (5), comprise an adhesive. The adhesive may be applied to the lower surfaces of the first and second elongated connectors (15 and 35), or to the upper surfaces of the first and second flat flexible components (5 and 25). Perforations (17 and 37) in the elongated connectors facilitate removal of the pulling elements (40 and 45) from the elongated connectors (15 and 35) following application of the bandage.

Lower surfaces of the first and second flat flexible components are covered (at least partially) with adhesive to facilitate attachment to the patient's skin. Such adhesives facilitate attachment and allow easy removal of the bandage after the wound or incision has healed. Protective films (not shown), removable by hand, serve as means for

protecting the adhesive on the first and second flexible flat components (5 and 35) prior to use of the bandage.

Fig. 2 depicts the bandage of Fig. 1 in a tensioned, but non-fixed state. More specifically, Fig. 2 depicts  
5 first and second flat flexible components (5 and 25) attached to the skin with adhesive. Tension has been applied to pulling elements (40 and 45) thereby drawing wound edges (20 and 42) toward one another, thereby effecting wound closure. Elongated connectors (15 and 35)  
10 have not yet been fixed by adhesive to the flat flexible components (5 and 25) thereby completing application.

Fig. 3 depicts the bandage of Fig. 1 in the tension and fixed (i.e., applied) state. Pulling elements 40 and 45 as shown in Figs. 1 and 3 have been removed along perforations  
15 17 and 37. Elongated connectors 15 and 35 are attached to flat flexible components 5 and 25 by adhesive. Cut-outs (47 and 49) in elongated connectors (35 and 15) are positioned directly above the wound or incision to facilitate drainage of exudates and application of medication.

Referring to Fig. 4, an alternative embodiment of the bandage of Fig. 1 is shown in which only a single elongated connector (15) is attached to the first flat flexible component (5). This embodiment is referred to herein as a wide key-hole embodiment.  
20

Referring to Fig. 5, a clear, breathable protective cover (51) having an adhesive strip (53) along the perimeter may be applied to protect the area to which a bandage of the present invention has been applied. Fig. 6 depicts the protective cover (51) applied to the skin over a bandage of  
25  
30 the present invention (1).

CLAIMS

1. A bandage for closing a wound comprising:
  - a) a first flat flexible component having adhesive on a lower surface and a plurality of first elongated connectors extending from one edge thereof in a first direction;
  - b) a second flat flexible component having adhesive on a lower surface and one or more second elongated connectors extending from one edge thereof in a second direction generally opposite to the first direction;
  - c) a first pulling element joined to said first elongated connectors and adapted for lateral translation of the first flat flexible component toward a wound edge;
  - d) a second pulling element joined to said second elongated connectors and adapted for lateral translation of the second flat flexible component toward the wound edge; and
  - e) means for attaching the first elongated connectors to the second flat flexible component and means for attaching the second elongated connectors to the first flat flexible component.
2. The bandage of Claim 1 wherein elements a) - d) are produced from a substantially inelastic material or are produced from an elastic material which is reinforced with an inelastic structural component thereby rendering the device substantially inelastic.
3. The bandage of Claim 1 which is adapted for removal of the first and second pulling elements following attachment of the bandage.



4. The bandage of Claim 1 wherein said first and second elongated connectors are interleaved.
5. The bandage of Claim 1 wherein the first elongated connectors are adjacent one another and centrally located, and the second elongated connectors flank the first elongated connectors at outside edges of the bandage.
6. The bandage of Claim 1, wherein the first and second pulling elements are rigid.
7. The bandage of Claim 1, wherein the first and second pulling elements are non-rigid, but are reinforced with a rigid element.
8. The bandage of Claim 1 wherein elements a) - d) are die cut from sheet stock.
9. The bandage of Claim 1 wherein the edges of the first and second flat flexible components which attach to the skin on opposing sides of a wound or incision are adapted to evert skin edges to promote wound healing.
10. The bandage of Claim 10 wherein the edges of the first and second flat flexible components are angled or curved to evert the skin edges.
11. The bandage of Claim 1, wherein a portion of the elongated connector is cut away to increase unobstructed surface area above the wound thereby facilitating drainage of exudates and application of medication.

12. The bandage of Claim 1, wherein the first and second flat flexible components are adapted for wound closure alignment.
13. The bandage of Claim 12 wherein said adaptation comprises alignment marks on the first and second flat flexible components for alignment with each other and/or with marks placed directly on skin.
14. The bandage of Claim 1, which is adapted for transdermal drug delivery.
15. The bandage of Claim 1 further comprising an elastic tension indication element.
16. The bandage of Claim 15 wherein the elastic tension indication element is removable with the pulling elements.
17. The bandage of Claim 1 further comprising a rigid polymer bar attached to the edges of the first and second flat flexible components which are nearest to and substantially parallel the wound or incision.
18. A method for closing a wound or incision comprising the steps of:
  - (a) providing a bandage for closing a wound comprising:
    - i) a first flat flexible component having adhesive on a lower surface and a plurality of first elongated connectors extending from one edge thereof in a first direction;
    - ii) a second flat flexible component having adhesive on a lower surface and one or more second elongated connectors extending from

- one edge thereof in a second direction generally opposite to said first direction;
- iii) a first pulling element joined to said first elongated connectors and adapted for lateral translation of the first flat flexible component toward a wound edge;
  - iv) a second pulling element joined to said second elongated connectors and adapted for lateral translation of the second flat flexible component toward the wound edge;
  - vi) means for attaching the first elongated connectors to the second flat flexible component and means for attaching the second elongated connectors to the first flat flexible component; and
- b) attaching said lower surface of said first flexible component to a patient's skin along a first side of a wound;
  - c) attaching said lower surface of said second flexible component to the patient's skin along a second side of said wound;
  - d) pulling simultaneously said first and second pulling elements until said elongated connectors are subjected to a tension sufficient to close the wound or incision;
  - e) attaching said first elongated connectors to said second flexible component; and
  - f) attaching said second elongated connectors to said first flexible component.

19. The method of Claim 18 further comprising the steps of:
- a) removing said first pulling element from said first elongated connectors; and
  - b) removing said second pulling element from said second elongated connectors.

20. The method of Claim 18 further comprising the steps of:
  - a) attaching said first pulling element to the patient's skin beside said second flat flexible component; and
  - b) attaching said second pulling element to the patient's skin beside said first flat flexible component.
21. The bandage of Claim 1 wherein the elongated connectors are sufficiently spaced-apart to facilitate lateral adjustment of the first flat flexible component relative to the second flat flexible component.
22. A protective bandage for application to the skin, the bandage comprising a breathable film with perimeter adhesive.

BANDAGE FOR WOUND OR INCISION CLOSURE

Abstract of the Disclosure

Disclosed is a bandage for closing a wound or incision,  
and methods for the use of same. The bandage comprises a  
5 first flat flexible component having adhesive on a lower  
surface and a plurality of first elongated connectors  
extending from one edge thereof in a first direction. The  
bandage further comprises a second flat flexible component  
having adhesive on a lower surface and one or more second  
10 elongated connectors extending from one edge thereof in a  
second direction generally opposite to the first direction.  
Pulling elements are joined to the first and second  
elongated connectors. Means are provided for attaching the  
first elongated connectors to the second flat flexible  
15 component and the second elongated connectors to the first  
flat flexible component.

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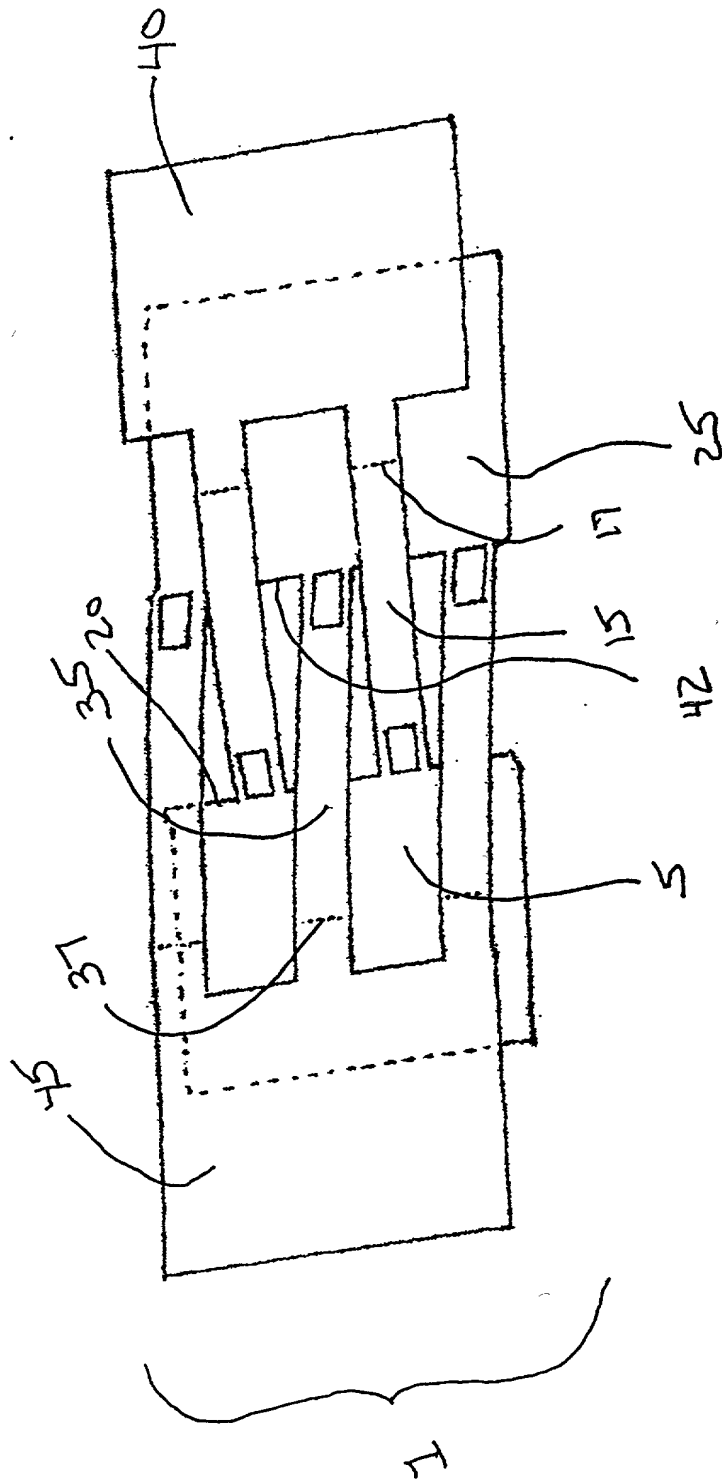


FIG. 1

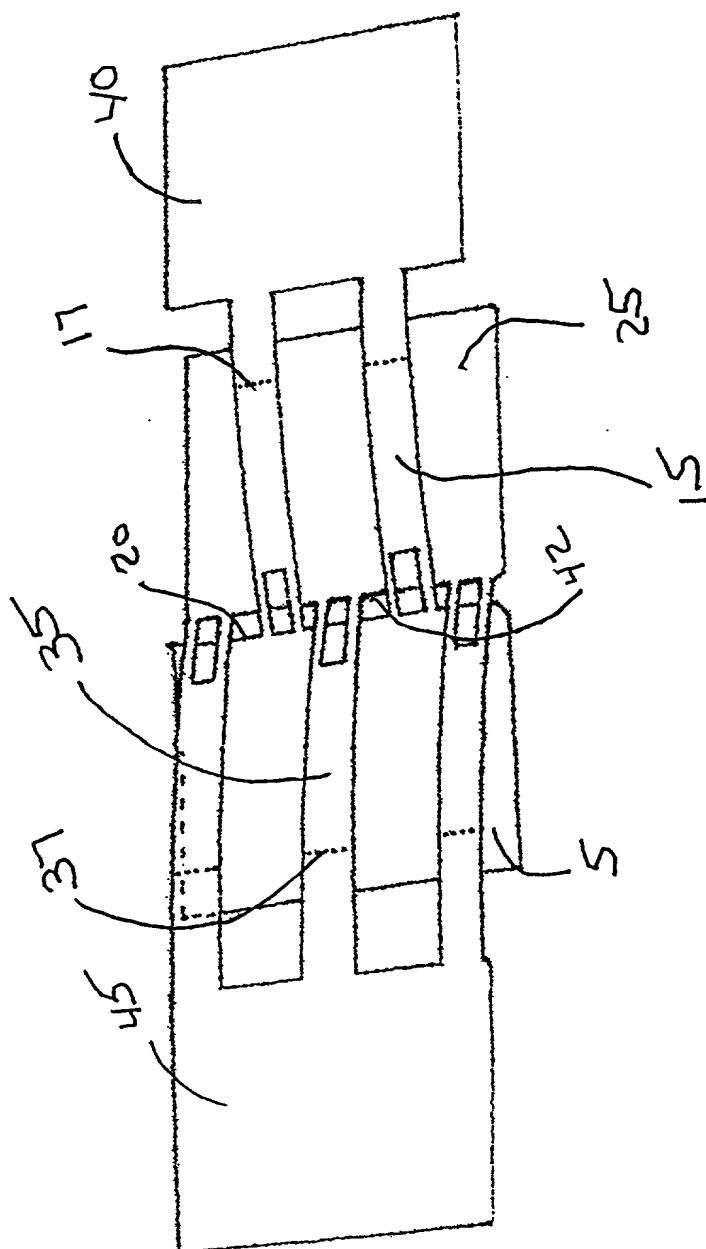


FIG. 2

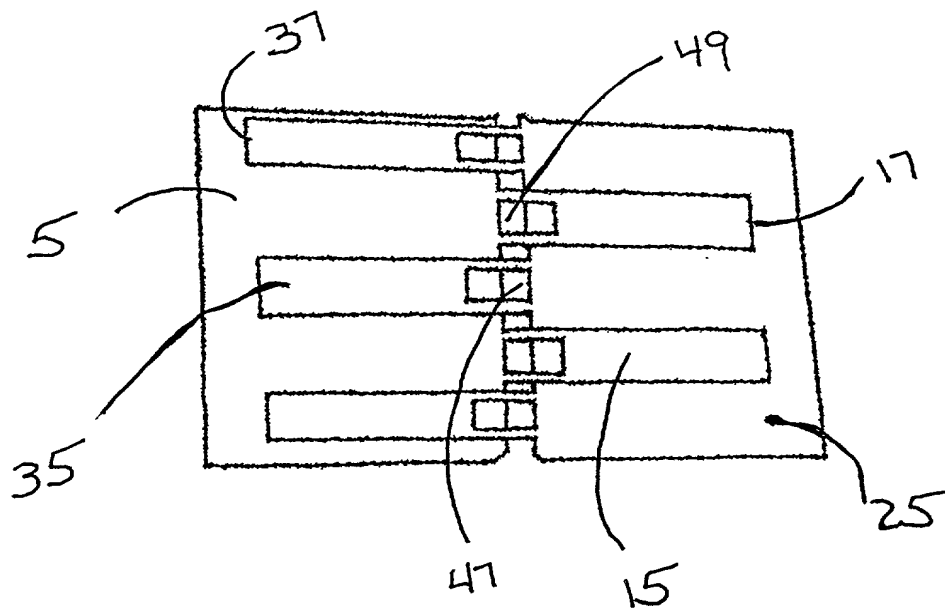


FIG. 3



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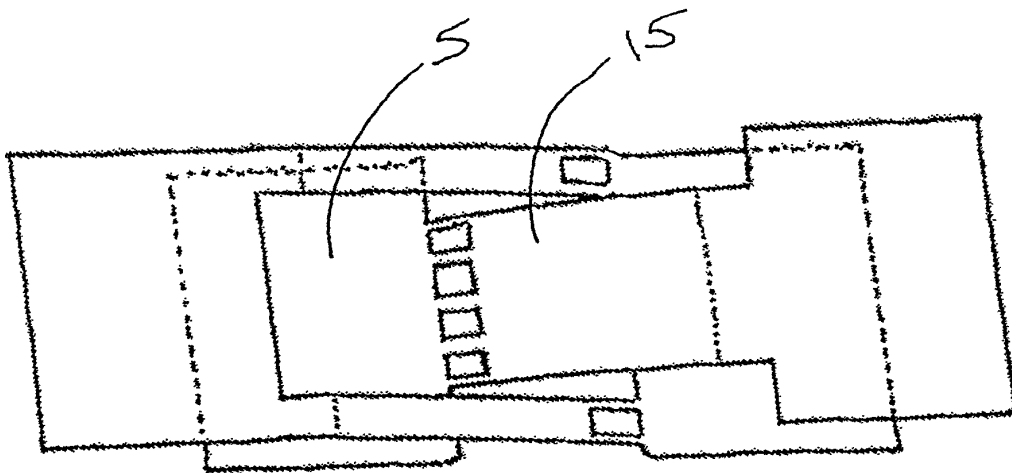


FIG. 4

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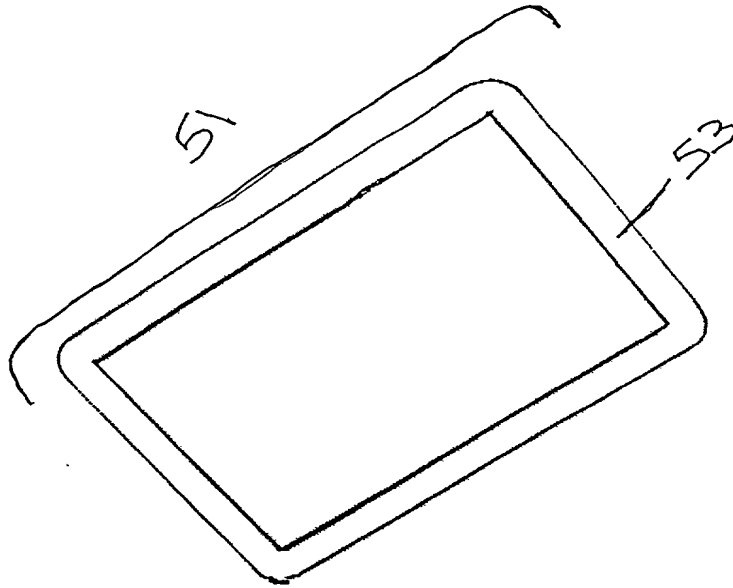


FIG. 5

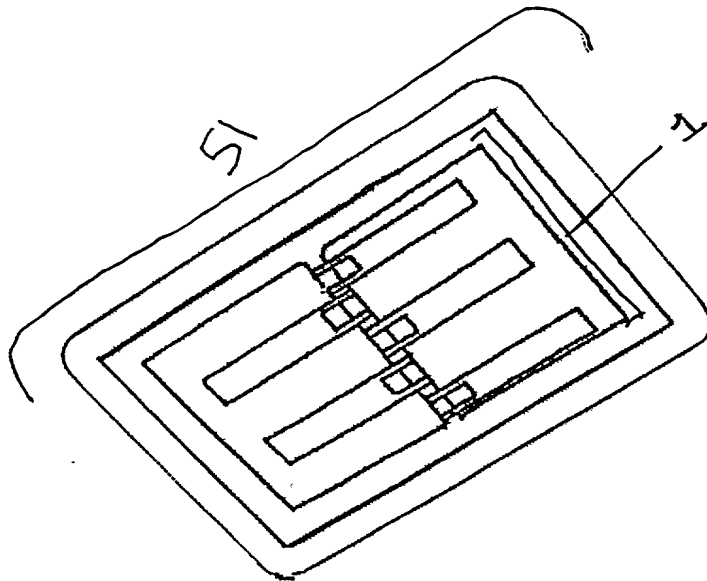


FIG. 6

## DECLARATION FOR PATENT APPLICATION

As a named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below next to my name;

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **BANDAGE FOR WOUND OR INCISION CLOSURE**, the specification of which

☒ is attached hereto.  
☐ was filed on \_\_\_\_\_ as Application Serial Number \_\_\_\_\_  
and was amended on \_\_\_\_\_  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

### Prior Foreign Application(s)

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed:

Country	Application Number	Date of Filing (day, month, year)	Date of Issue (day, month, year)	Priority Claimed Under 35 U.S.C. 119
				Yes <input type="checkbox"/> No <input type="checkbox"/>
				Yes <input type="checkbox"/> No <input type="checkbox"/>

### Prior United States Provisional Application(s)

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below:

Application Number	Filing Date

**Prior United States Application(s)**

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s), or §365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

Application Serial Number	Date of Filing (day, month, year)	Status - Patented, Pending, Abandoned

As a named inventor, I hereby appoint the following registered practitioner to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Kevin M. Farrell, 35,505

All correspondence and telephone communications should be addressed to Kevin M. Farrell, Farrell & Associates, P.C., P.O. Box 999, York Harbor, ME 03911, telephone number (207) 363-0558, which is also the address and telephone number of each of the above listed attorneys.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

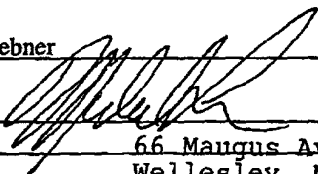
Inventor's

Full Name:

Michael ... Lebner

Inventor's

Signature:



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